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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,393	01/31/2002	Francis Moussy	98-2163-P	3741

23413 7590 09/20/2004

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/066,393	Applicant(s) MOUSSY ET AL.	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 2-7, 12, 13, 15, 16, 20-29 and 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 8-11, 14, 17-19 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 2-7, 12, 13, 15, 16, 20-29, and 31-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper Numbers 11 and 15. Claim 9 was rejoined with the elected claims because it is an intervening claim to claim 10 which was said to be drawn to the elected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 17-19, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Fearnot et al (US 5,609,629). Fearnot anticipates the claim language where the implant with the outer surface as claimed is met by implant (10) with structure (12) and base material (14) of Fearnot; see Figure 2 and column 6. The bioactive polymer layer with nanoparticles or liposomes as claimed is met by the disclosure on column 14, lines 12-29 of Fearnot. The bioactive polymer layer as claimed is layer (18) of Fearnot which contains the bioactive polymer heparin (a mucopolysaccharide); see column 7, lines 30-60. Heparin is also the bioactive tissue response modifier as claimed or one of the other compounds when used in conjunction therewith; column 3, lines 30-49 of Fearnot.

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Claims 1, 8-11, 14, and 30 are rejected under 35 U.S.C. 102(b)* as being anticipated by Hubbell et al (US 5,801,033). Hubbell anticipates the claim language where the tissue response modifier is the agent or material released by the encapsulated cells or encapsulated pharmaceuticals to have a therapeutic purpose in the patient; see the abstract, column 5, line 40 to column 6, line 34 and column 10, line 33 to column 11, line 51. The polymer of the bioactive polymer layer as claimed is the encapsulating polymer that forms microcapsules or microspheres; see column 12, line 62 to column 13, line 18. These encapsulated cells or pharmaceuticals are coated on medical devices; see *supra*.

With regard to claim 9, the gels of Hubbell are hydrogels since they are hydrophilic; see column 10, line 33 to column 11, line 51.

*The effective filing date of the present claims is considered to be January 31, 2002. However, if upon more careful analysis, the claims are found to have an effective filing date of the provisional application, then the Hubbell reference would still constitute a valid Section 102(e) reference.

Response to Arguments

Applicant's arguments filed May 17, 2004 have been fully considered but they are not persuasive.

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In response to the traversal of the Fearnot rejection that Fearnot does not disclose the bioactive material in the porous layer, the Examiner asserts that the claim does not require that the bioactive material be in the porous polymer layer so this argument is not commensurate with the scope of the claim.

In response to the traversal of the Hubbell rejection that the polymer layer and biological material are discrete layers, the Examiner views the polymer and biological material as different parts of the same layer as the polymer forms a coating around the biological materials or pharmaceuticals to form microcapsules. The polymer is thus part of the same layer as the biological material or pharmaceutical.

Conclusion

The prior art cited that was not applied is considered relevant to the claimed invention.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilit
Primary Examiner
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